States, the submission and certification statement or application for exemption shall contain the signature, name, and address of the manufacturer's attorney, agent, or other authorized official who resides or maintains a place of business in the United States.

(c) The manufacturer shall send three copies of the submission and certification statement or application for exemption to FDA. The outside of the shipping container shall be marked as ''Submission for the Dissemination of Information on an Unapproved/New Use.'' The manufacturer shall send the submission and certification statement or application for exemption to the appropriate FDA component listed in paragraphs (c)(1) through (c)(3) of this section.

(1) For biological products and devices regulated by the Center for Biologics Evaluation and Research, the Advertising and Promotional Labeling Staff (HFM–602), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448;

(2) For human drug products, biological products, and devices regulated by the Center for Drug Evaluation and Research, the Division of Drug Marketing, Advertising, and Communications (HFD–42), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or

(3) For medical devices, the Promotion and Advertising Policy Staff (HFZ–302), Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850.

(d) The 60-day period shall begin when FDA receives a manufacturer's submission, including, where applicable, a certification statement or an application for an exemption.

[63 FR 64581, Nov. 20, 1998, as amended at 70 FR 14980, Mar. 24, 2005]

§ 99.203 Request to extend the time for completing planned studies.

(a) A manufacturer may request, prior to or at the time of making a submission to FDA under § 99.201, that FDA extend the 36-month time period for completing the studies and submitting a supplemental application for the new use that is the subject of the information to be disseminated. Such request must set forth the reasons that such studies cannot be completed and submitted in a supplemental application within 36 months.

(b) A manufacturer who has certified that it will complete the studies necessary to submit a supplemental application for a new use within a specified period of time from the date that dissemination of information under this part can begin under § 99.201(a)(4)(ii), but later finds that it will be unable to complete such studies and submit a supplemental application within that time period may request an extension of time from FDA. The manufacturer, in its request for extension, shall identify the product, the new use, and shall:

(1) Describe the study or studies that cannot be completed on time and explain why the study or studies cannot be completed on time;

(2) Describe the current status of the incomplete study or studies and summarize the work conducted, including the dates on which principal events concerning the study or studies occurred; and

(3) Estimate the additional time needed to complete the studies and submit a supplemental application. The requested extension shall not exceed an additional 24 months.

(c) The manufacturer shall send three copies of the request for extension to the same FDA office that received the manufacturer's initial submission and certification statement. The outside of the envelope shall be marked as ''Request for Time Extension—Dissemination of Information on an Unapproved Use.''

§ 99.205 Application for exemption from the requirement to file a supplemental application.

(a) In certain circumstances, described in paragraph (b) of this section, a manufacturer may submit an application for an exemption from the requirement to submit a supplemental application for a new use for purposes of disseminating information on that use.

(b) The manufacturer's application for an exemption shall identify the